

## **REMARKS**

The present Amendment is in response to the Examiner's Office Action mailed June 3, 2004. Claims 31 and 108 are amended. Claims 1-38 and 40-133 are now pending in view of the above amendments.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicants request that the Examiner carefully review any references discussed below to ensure that Applicants' understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

### **I. Rejection Under 35 U.S.C. § 112, Second Paragraph**

The Examiner rejects claim 131 under 35 U.S.C. § 112, Second Paragraph for indefiniteness on the grounds that there is no support in the specification for placing 100 ug of protein into a 10mm conduit. In response, Applicants note that support for the recited limitation can be found in amended paragraph 0067 in the Amendment and Response filed by the Applicants on March 5, 2004. The prompt removal of this rejection is therefore respectfully requested.

### **II. Rejections Under 35 U.S.C. § 103**

The Examiner rejects claims 22, 24-26, 27-31, 40-42, 45-49, 51, and 54-56 under 35 U.S.C. § 103 as being unpatentable over *Peulve* (U.S. Patent Application Publication No. 2002/0071828) in view of *Leong* '765 (U.S. Patent No. 5,256,765).

*Peulve* is cited for teaching a nerve guide polymer in the shape of a tube. In addition, the Office Action cites *Peulve* as disclosing that a gene delivery system can be incorporated in the nerve guide. As the Examiner notes, however, *Peulve* does not teach or suggest

poly(phosphoester) materials for use in nerve guide conduits. The Office Action therefore cites *Leong '765*'s teachings of poly(phosphoester) materials, which are disclosed in *Leong '765* as biodegradable and useful in a therapeutic agent delivery vehicle but are not disclosed for use with nerve tissues.

Applicants traverse the Examiner's rejection for obviousness on the grounds that the references – either individually or in combination – fail to teach or suggest each and every element of the rejected claims. Particularly, Applicants respectfully note that a very significant gap exists between the cited references and the claims as presently recited. As noted above, *Leong '765* does not disclose that poly(phosphoester) materials are compatible with nerve tissues or can serve as nerve guide conduits. In fact, it is well known that most biodegradable materials are typically failures when applied to nerve tissues. For example, otherwise biocompatible materials often lead to inflammatory responses from nerve tissues that render the materials a failure. See *Specification* at page 4, lines 1-9 (“[S]ome of the materials identified above have led [sic] to inflammatory reactions in the test animals and have failed to exclude scar tissue formation within channels . . . Moreover, the loss of sensory or motor function is still the most common outcome of such laboratory experiments.”). In other words, the mere status of a material as generically biocompatible does not teach or suggest to one skilled in the art that the material is specifically compatible with nerve tissues.

Despite the difficulty in obtaining materials that are compatible with nerve tissues, Applicants have made the unexpected discovery that poly(phosphoester) materials are in fact compatible with nerve tissues and can serve as a nerve guide conduit. Since there is not a recognition in the art that poly(phosphoester) materials can be so used, Applicants' discovery of this unexpected feature of poly(phosphoester) materials provides for unexpected new avenues of research and product development to incorporate poly(phosphoester) materials in the nerve guide conduit field. In view of this unexpected improvement, Applicants maintain that they are entitled to a patent and respectfully request that the Examiner withdraw the present rejection for obviousness.

In addition, Applicants also traverse the Examiner's rejection for obviousness on the grounds that the Examiner's combination of *Peulve* with *Leong '765* is improper. The prior art must teach or suggest making a modification to the prior art in order to render a claimed invention obvious. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). In other words, one

must be motivated **by the prior art** to make the modification necessary to arrive at the present invention. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). Absent such motivation, a rejection based on a combination of references is unsupported and any rejection based on such a combination must be withdrawn. In the present case, there is no motivation to combine *Peulve* with *Leong* '765 because, although it was known that poly(phosphoester) materials were biocompatible with other bodily tissues, it was unknown that poly(phosphoester) materials were compatible with nerve tissues. As noted above, this is not a trivial distinction. Applicants respectfully assert that the only way *Peulve* can be combined with *Leong* '765 is through impermissible hindsight, using the teachings of the present application as a blueprint to fill in the gaps between the cited references.

Accordingly, Applicants respectfully assert that the independent claims 22 and 47 are patentable over the cited references because; (1) the references cannot be combined absent impermissible hindsight; and (2) assuming, *arguendo*, that the references are combined, they do not teach all the claimed features of the invention. For at least the foregoing reasons, Applicants also respectfully assert that claims 24-26, 27-31, 40-42, 45, 46, 48, 49, 51, and 54-56 are also patentable over the cited references.

In addition, claims 27-29 are also patentable over *Peulve* and *Leong* '765 because obtaining the cited porosities is not a trivial matter for poly(phosphoester) materials, nor are they selected as claimed exclusively for biodegradability issues. Rather, as stated in the specification: "[The permeability of nerve conduits] determines the inclusion or exclusion of factors that affect nerve regeneration." Specification, p. 21, ll. 9-12. In other words, the claimed porosities are selected to facilitate communication between the inside and the outside of the nerve guide in terms of diffusion of soluble factors, nutrients, and waste products.

As noted by the Examiner, neither of *Peulve* and *Leong* '765 disclose porosity nor provide any motivation to obtain the claimed porosities. Therefore, the cited references cannot provide a motivation, suggestion, or teaching of the desirability of the claimed combinations, and a prima facie case for obviousness has not been presented. In the event the Examiner continues with this rejection, he is requested to cite a specific reference that teaches or suggest the desirability of the specifically claimed porosities, in combination with the other claimed features of the invention.

The Examiner rejects claims 32-38 under 35 U.S.C. § 103 as being unpatentable over *Peulve* in view of *Leong* '765 and further in view of *Li* (U.S. Patent No. 5,026,381). The Examiner also rejects claim 41 over *Peulve* in view of *Leong* '765 and further in view of *Davis* (U.S. Patent Application Publication No. 2002/0044972). The Examiner further rejects claims 43 and 44 over *Peulve* in view of *Leong* '765 and further in view of *Neuman* (U.S. Patent Application Publication No. 2003/0027779). In response, Applicants respectfully assert that claims 32-38, 41, 43, and 44 are patentable over *Peulve* in view of *Leong* '765 for at least the reasons presented hereinabove with respect to independent claim 22, from which each of claims 32-38, 41, 43, and 44 depend. *Li*, *Davis* and *Neuman* cannot overcome the deficiencies of *Peulve* and *Leong* '765 in this regard.

The Examiner rejects claim 50 under 35 U.S.C. § 103 as being unpatentable over *Peulve* in view of *Leong* '765 and further in view of *Mao* '737 (U.S. Patent No. 6,485,737).

In response to the rejection of claim 50, the Applicants direct the Examiner to the Applicants' Supplemental Reply Under 37 C.F.R. § 1.111 with Amendment filed January 8, 2004 and the accompanying Declaration of Kam Leong under 37 C.F.R. § 1.132. In that response, Applicants removed *Mao* '737 as a prior art reference due to Kam Leung's contributions to the *Mao* '737 reference. Accordingly, the prompt removal of the rejection of claim 50 is respectfully requested.

The Examiner also rejects claims 52 and 53 over *Peulve* in view of *Leong* '765 and further in view of *Schwenderman* (U.S. Patent Application Publication No. 2002/0009493). Applicants respectfully assert that claims 52 and 53 are patentable over *Peulve* in view of *Leong* '765 and *Schwenderman* for at least the reasons presented hereinabove with respect to independent claim 47, from which each of claims 52, and 53 depend.

The Examiner rejects claim 57 over *Peulve* in view of *Leong* '765 and further in view of *Stone* (U.S. Patent No. 5,258,043). The Examiner also rejects claims 98-133 "for the same reasons as their corresponding claims above." Office Action, p. 9.

Similar to claims 22 and 47, independent claims 57, 98, and 99 recite, *inter alia*: "A nerve guide conduit comprising a poly(phosphoester) polymer in the shape of a tube having a diameter, a first end, a second end, and a wall having an outer surface and a luminal surface." As noted above, neither of *Peulve* and *Leong* '765 disclose each of the foregoing limitations. In addition, *Stone* cannot overcome the limitations of *Peulve* and *Leong* '765 in that *Stone* has no

teaching or suggestions whatsoever related to poly(phosphoester) materials. Accordingly, it is respectfully asserted that claims 57, 98, and 99 are patentable over the cited references.

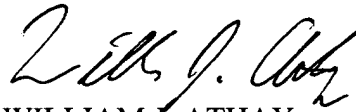
Claims 100-133 depend from claim 99 and include the limitations therein. Accordingly, claims 100-33 are patentable over the cited references for at least the reasons that claim 99 is patentable over the cited references. The prompt removal of this rejection is therefore respectfully requested.

### **CONCLUSION**

In view of the foregoing, Applicants believe the claims as amended are in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, or which may be overcome by an Examiner's Amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 30th day of November, 2004.

Respectfully submitted,



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